EPO
Epidemiology Program Office
Issue 2

ADS Newsletter
Office of the Associate Director for Science
April 2002

Human Subjects Review Tracking

The first step in the human subjects review (HSR) process begins when the investigator submits a request for a human subjects review tracking number (HSR#) to the EPO Office of the Associate Director for Science (OADS). Projects that involve human participants, either through direct interaction or collection/analysis of identifiable data, may need to undergo human subjects review. In general, if an investigation or evaluation takes more than one day of an investigator's time, it is a good idea to consult the EPO supervisor to see if it needs an HSR#. Examples of projects that need HSR numbers include the following:

- Focus group studies;
- Outbreak investigations;
- Systematic analyses of existing data;
- Intervention studies; or
- Formal research.

In most instances, work on a project should *not* begin until the principal investigator has received an HSR#. One exception to this practice is in an outbreak setting where prompt action is required to prevent further cases of the condition; in this situation, an HSR# should be requested as soon as possible after investigation has begun. Not all HSR projects will be considered research or require IRB review.

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Ethical Dilemmas in Public Health

Scenario 1 - An EIS Officer conducted a follow-up to an Epi-Aid with a colleague. The Officer performed all the analyses, but his colleague had helped with the data collection. The colleague focused on other activities. The Officer asked the colleague if he would be interested in writing up the evaluation, but he declined. When the manuscript was complete and successfully through clearance, the colleague wanted co-authorship.

Issues – How should the Officer handle this situation?

The designation of authorship should be addressed at the beginning of an investigation and should be documented in writing. Roles may change as the investigation progresses, so the issue surrounding roles and credit must be revisited and discussed throughout the process of investigation, analysis, and manuscript writing. In this situation, perhaps a way of resolving the issue is by listing the colleague in the Acknowledgements, because of his limited contribution to the work.

Scenario 2 – A supervisor made inappropriate determinations of several research studies, designating them as non-research. A later discovery revealed that the supervisor was aware that the projects were research, but was trying to pass them off as non-research.

Issues – What are some of the concerns in this situation?

Supervisors are often sympathetic to the people they oversee and are dedicated to accomplishing the public health mission. Unfortunately, this attitude can prevent their making rational, ethical decisions. Classifying a project as research may mean that project implementation will be delayed, or even prevented from being implemented. Although there may be good intentions in bypassing the process, a supervisor must adhere to ethical and legal obligations. The most important concern is protecting the human subjects in research. Their trust and cooperation are critical to the success of the research.

If you have ethical scenarios you would like to share, please submit them to Aun Lor (alor@cdc.gov).

Defining Research and Non-research

*The Code of Federal Regulation Title 45 "Public Welfare," Part 46 "**Protection of Human Subjects**,"* or 45CFR46*, also* known as the **Common Rule**, *defines "**research**" as "a systematic investigation, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable knowledge**."*

It is often difficult in public health to distinguish research from non-research. Three general non-research categories are program evaluation, surveillance, and disease control and prevention activity. These activities can often generate "generalizable knowledge," however, if the **primary intent** is to benefit study participants or the communities from which they come, then they are generally not considered research.

Program evaluation

- Non-research if the intent is to
  - assess success of an established intervention, and
  - evaluate information used for feedback into program (management).
- Research if the intent is to
  - test an intervention, or
  - conduct a systematic comparison of standard and nonstandard interventions.

Surveillance

- Non-research if the intent is to
  - conduct regular, ongoing collection and analyses to measure occurrence of a health problem and scope of data is health condition or disease, demographics, and known risk factors;
  - invoke public health mechanisms to prevent or control disease or injury.
- Research if the intent is to
  - compare different surveillance approaches,
  - test hypothesis, and
  - conduct subsequent studies using cases identified through surveillance.

Disease control and prevention

- Non-research if the intent is to
  - solve an immediate health problem with no testing of methods or interventions.
- Research if the intent is to
  - store samples for future use,
  - perform additional analyses beyond control of immediate problem, and
  - test investigational drugs.

CDC Guidelines for Defining Public Health Research and Non-research can be found at: http://www.cdc.gov/od/ads/hsrdocs.htm.

Protocol Preparation

A well-formatted protocol facilitates rapid IRB review. CDC guidelines for writing a protocol are available to help the investigator prepare a protocol for submission. Generally, the following protocol format is suggested as a guide. Some of the information listed may not be relevant to all projects, and others may need to be included.

- Project Overview
- Introduction
- Procedures / Methods
  - Design
  - Study Population
  - Variables / Interventions
  - Data Handling and Analysis
  - Handling of Unexpected or Adverse Events
  - Dissemination, Notification, and Reporting of Results
- References
- Appendix Materials

Additional information required is listed below and should be included in the protocol. Others may or may not apply to a protocol as noted by *.

- CDC investigator's role
- Risks
- Methods to minimize risks
- Anticipated benefits
- Risk/Benefit Ratio
- *Vulnerable population(s)
- Documentation of informed consent
- *Justification for waiver/alteration of informed consent
- *Documentation of assent for children
- *Documentation of parent's / guardian's permission
- Protection of privacy and confidentiality
- *Assurance/Certificate of Confidentiality
- Other relevant materials

The complete CDC guidelines for developing a protocol can be found at the CDC ADS Website at http://www.cdc.gov/od/ads/hsr2.htm.

IRB Updates

New IRB Deferral Form

CDC Form .1256 - Request for deferral of New Protocol to another institutional IRB

The CDC Office of the Associate Director for Science (OADS) has developed a new form for use when an investigator wishes to defer a protocol review to another institutional IRB.

The new deferral and other IRB forms can be found at the CDC ADS Websites below:

Intranet - http://intranet.cdc.gov/od/ads/hsrirb.htm
Internet - http://www.cdc.gov/od/ads/hsrirb.htm

AAHRPP "OPEN FOR BUSINESS," READY TO ACCEPT APPLICATIONS FOR ACCREDITATION

Press Release:
Washington, D.C., February 26, 2002--At a press briefing today, staff and board members of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) announced that the new accrediting entity is accepting applications from organizations that conduct or review research involving human participants. Representatives from the U.S. Department of Health and Human Services and the National Science Foundation were on hand to express their support for this type of accreditation.

"I am very pleased to announce the release of AAHRPP's final standards, final procedures, and our fee structure," said Executive Director Marjorie Speers, Ph.D. "In other words, AAHRPP is open for business."

AAHRPP's Interim Accreditation Standards and Procedures, which were released in October for a public comment period, have been finalized and approved by AAHRPP's Board of Directors. Those standards were tested and refined during several AAHRPP pilot site visits, including one for intramural programs at the National Institutes of Health. "These are standards that will serve research participants and patients, researchers, research institutions, and the general public very well," said board President

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David Skorton, M.D., Vice President for Research at the University of Iowa. AAHRPP standards meet all regulatory requirements related to human participant protections and, in some cases, exceed them.

The 21-person AAHRPP Board of Directors, installed in October, has broad representation, encompassing researchers, administrators of both human participant protection programs and the institutions in which they reside, and the public-five directors are patient or research participant advocates.

Eve Slater, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services, lauded this type of accreditation as one of the "absolutely essential building blocks" to improving research protections, and ultimately, the safety and health of the American public. Dr. Slater added that private accreditation is preferable to mandatory accreditation.

"It's very encouraging to see organizations like AAHRPP attempt to create a culture of common sense--an ethical culture--which is absolutely required for this process to move forward," said Philip Rubin, Ph.D., Director of the Division of Behavioral and Cognitive Sciences at the National Science Foundation. He stressed the importance of AAHRPP accreditation being offered to a broad array of research programs, including those in the behavioral and social sciences.

The new entity uses a voluntary, peer-driven, educational model of accreditation. AAHRPP is the first organization to be formed specifically for the purpose of accrediting human research protection programs, and will offer such accreditation widely to all relevant entities.

AAHRPP is an independent, nonprofit organization supported through applicant fees. Application information and materials are available on the Web at www.aahrpp.org, or by contacting the Washington, D.C., headquarters.

AAHRPP is a national, nonprofit accrediting organization incorporated in April 2001. AAHRPP's founding member organizations are the Association of American Medical Colleges, Association of American Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Association of State Universities and Land-Grant Colleges, National Health Council, andPublic Responsibility in Medicine and Research. For more information, visit www.aahrpp.org.

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Important Websites

CDC IRB Intranet Websites
http://inside2.od.cdc.gov/adshsp/source/query.asp

CDC ADS Internet Websites
http://www.cdc.gov/od/ads/index.htm

CDC ADS Intranet Websites
http://intranet.cdc.gov/od/ads/index.htm

Office for Human Research Protections
http://ohrp.osophs.dhhs.gov/index.html

Office of Research Integrity
http://www.ori.dhhs.gov/

EPO Internet Websites
http://www.cdc.gov/epo/

EPO Intranet Websites
http://intranet.cdc.gov/epo/home.htm